PART I - ADMINISTRATIVE

Section 1. General administrative information

Title of project

Infrastructure To Complete FDA Registration Of Erythromycin

BPA project number: 20059
Contract renewal date (mm/yyyy): ☐ **Multiple actions?**

Business name of agency, institution or organization requesting funding

Business acronym (if appropriate) UI-FWR

Proposal contact person or principal investigator:

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NPPC Program Measure Number(s) which this project addresses
7.2 and 7.4 Several components of each

FWS/NMFS Biological Opinion Number(s) which this project addresses

Other planning document references
Snake River Recovery Task 4.1

Short description
Provide the infrastructure needed in the Columbia River basin to maintain and complete the FDA registration of erythromycin feed additive, a necessary therapeutant for sustained hatchery production and maintenance of captive broodstocks of salmon

Target species
All salmon, with highest priority for chinook and sockeye

Section 2. Sorting and evaluation

Subbasin
Systemwide

Evaluation Process Sort

CBFWA caucus	Special evaluation process	ISRP project type
Mark one or more	If your project fits either of these	Mark one or more categories

caucus	processes, mark one or both	
☒ Anadromous fish ☐ Resident fish ☐ Wildlife	☒ Multi-year (milestone-based evaluation) ☐ Watershed project evaluation	☐ Watershed councils/model watersheds ☒ Information dissemination ☐ Operation & maintenance ☐ New construction ☒ Research & monitoring ☒ Implementation & management ☐ Wildlife habitat acquisitions

Section 3. Relationships to other Bonneville projects

Umbrella / sub-proposal relationships. List umbrella project first.

Project #	Project title/description

Other dependent or critically-related projects

Project #	Project title/description	Nature of relationship
	Captive Broodstock Operations	Provides the drug needed for control of bacterial kidney disease
	Artificial Production	Drug used for control of bacterial kidney disease in production of chinook, coho, and sockeye

Section 4. Objectives, tasks and schedules

Past accomplishments

Year	Accomplishment	Met biological objectives?

Objectives and tasks

Obj 1,2,3	Objective	Task a,b,c	Task
1	Provide an infrastructure to keep erythromycin registration efforts viable in the Columbia River Basin		Provide funding for PI and staff assistant to provide interim management and oversight of erythromycin feed additive and provide responses to all FDA querry
2	Increase visibility and dialog with FDA and other entities to resolve outstanding issues	a	Hold meetings with FDA and regional/governmental and non governmental supporters

2		b	Give papers on the status of erythromycin registration at conferences dealing with drug registration and at meetings that address aquaculture risk assessment
3	Assemble regional fish health and other scientists to assist in design or implementation of any additional studies needed to satisfy FDA		Increase active communication with the NCTR lab and others in the international/national community capable with resolving elements of risk assessment

Objective schedules and costs

Obj #	Start date mm/yyyy	End date mm/yyyy	Measureable biological objective(s)	Milestone	FY2000 Cost %
1	10/1999	9/2001	Provide the staff needed to increase turnaround time and use assistance offered by regional fish health personnel to resolve outstanding issues with FDA	Summaries of literature provided to FDA, regular dialogs established with key regional personnel, active dialog with potential drug companies.	60.00%
2	11/1999	9/2000	Provide increased visibility of the need to complete approval of erythromycin within FDA and governmental and non governmental agencies	Video and direct conferences provided and papers presented at appropriate meetings	25.00%
3	12/1999	9/2001	Assemble regional fish health and other scientists to assist with additional studies needed for FDA	Meet with NCTR staff and regional scientists, and others in profession and resolve any remaining FDA's questions	15.00%
				Total	100.00%

Schedule constraints

This project is constrained by institutional inertia within FDA that delays a rapid response. However, support from a concerted regional effort will leverage far greater visibility than during the past 2 years and thereby improve the response rate.

Completion date
2001

Section 5. Budget

FY99 project budget (BPA obligated):

FY2000 budget by line item

Item	Note	% of total	FY2000
Personnel	Principal Investigator and Staff Assistant	%41	29,421
Fringe benefits	Principal Investigator and Staff	%13	9,204
Supplies, materials, non-expendable property	Copies, reports, page charges and slides for presentations	%5	3,700
Operations & maintenance	Phone, postage, fax, FedEx	%2	1,600
Capital acquisitions or improvements (e.g. land, buildings, major equip.)		%0	
NEPA costs		%0	
Construction-related support		%0	
PIT tags	# of tags:	%0	
Travel	Meetings and Negotiations	%14	9,920
Indirect costs	31.5% of direct costs	%24	17,177
Subcontractor		%0	
Other		%0	
TOTAL BPA FY2000 BUDGET REQUEST			$71,022

Cost sharing

Organization	Item or service provided	% total project cost (incl. BPA)	Amount ($)
Washington Department of Fish and Wildlife	Maintain INAD infrastructure for artificial production, provide assistance in sediment study, provide leadership and oversight through PNFHPC subcommittee on therapeutants	%14	20,000
Idaho Department of Fish and Game	Maintain INAD infrastructure for artificial production, provide assistance with data recovery for risk assessment	%7	10,000
Oregon Department of Fish and Wildlife	Maintain INAD infrastructure for artificial production, provide assistance with data recovery for risk assessment	%11	15,000
US Fish and Wildlife Service	Maintain INAD infrastructure for artificial production for Service and Columbia River Indian Tribes, provide communications through PNFHPC, provide national support for drug registration efforts	%14	20,000
National Marine Fisheries Service	Maintain INAD infrastructure for captive broodstock	%4	5,000
Total project cost (including BPA portion)			$141,022

Outyear costs

	FY2001	FY02	FY03	FY04
Total budget	$70,438			

Section 6. References

Watershed?	Reference
☐	NMFS. 1995. Proposed recovery plan for Snake River salmon, National Marine Fisheries Service.
☐	Power Planning Council. 1994. Columbia River Basin Fish and Wildlife Program. Portland Oregon.
☐	
☐	

PART II - NARRATIVE

Section 7. Abstract

This project provides critical support to continue and enhance an ongoing scientific and technical dialog between the University of Idaho (UI) and the US Food and Drug Administration (FDA) to resolve outstanding elements and achieve approval of erythromycin feed additive (Aquamycin) to control bacterial kidney disease in salmon. Erythromycin is needed for effective fish health management of bacterial kidney disease in salmon stocks reared in the Columbia River basin.

Legal access to erythromycin feed additive is currently provided for fish and wildlife agencies and tribes in the region through a coordinated investigational new animal drug permit held at the UI. Since 1995, the UI has assumed the additional interim responsibility for manufacturing this premix that is used to create medicated fish feeds used by agencies throughout the region. Although all the research to define the efficacy, target animal safety, residues in edible fish flesh, and safe field use of the feed products is completed, and has been determined satisfactory by FDA, outstanding new elements and institutional forces never anticipated at the beginning of the project impede the final approval.

This new initiative will provide funding for an infrastructure that will keep this important project viable. This infrastructure will increase the frequency and extent of dialog between UI and FDA, provide a pro-active promotion of the need for final approval within governmental and non-governmental institutions, and provide a rapid access to fish health practitioners and scientists who can assist in providing or implementing any further data collection necessary to satisfy FDA and achieve approval of this substance. These efforts will enhance the profile of erythromycin feed additive and reassure potential drug company sponsors that this product can be marketed successfully.

Section 8. Project description

a. Technical and/or scientific background

Erythromycin is the drug of choice for treatment of bacterial kidney disease in salmonids (Austin 1985; Elliott et al 1989; Evenden et al 1993), and is used in captive brood rearing and general hatchery production of salmon, including threatened and endangered stocks in the Snake River basin (Moffitt 1998). Erythromycin feed additive for salmon has not been approved by the US Food and Drug Administration

and legal access to erythromycin medicated feed is available only through Investigational New Animal Drug Permits (INADs) (Moffitt 1991; Moffitt and Haukenes 1995; Greenlees 1997).

The requirements for labeling a substance for approved use in food fish (FDA approval) include data to support the efficacy (lab and field trials), target animal safety, human safety, environmental impact, and manufacturing details. The specific requirements of each of these is detailed by FDA and reported in the federal register.

University of Idaho has played a key role in conducting the research needed to approve erythromycin for control of bacterial kidney disease in salmon, with funding from the Department of Agriculture, Bonneville Power, and the US Fish and Wildlife Service (Moffitt 1991; 1992; 1998; Peters and Moffitt 1995). Bonneville Power supplied the largest portion of funds for studies (from 1989-1996) that provided pivotal and supportive data and infrastructure to achieve FDA drug registration. Pivotal research included studies to: 1) determine an appropriate carrier for use in fish feeds; 2) determine the appropriate dosage and duration (efficacy) in the laboratory and the field; 3) define the limits of safe administration to the target animals, and 4) define the time needed post therapy for depletion of erythromycin residues in muscle tissues to levels considered safe for human consumption.

In the initial contact of work with Bonneville (DE-PS79-89BP96247), costs of providing details regarding manufacturing were omitted, as the project with the assistance from the NRSP-7 (Department of Agriculture) program through FDA had identified a drug company that was willing to sponsor the approved product and provide for test material for trials. The initial contract included a limited approach to assessment of environmental impact, and did not consider risks of resistant human microorganisms. As the project progressed, FDA began to rethink the requirements to satisfy the environmental and human risks, and the private drug company that agreed to sponsor the project was purchased by another drug company, and then that entity was purchased again by yet another company. In 1995, the drug company dropped support for the project, likely due to low margin anticipated from manufacturing, from delays in FDA approvals, and general lack on interest in aquaculture drugs.

In 1996, at the request of UI and with support from regional agencies, the Lower Snake Compensation Program (US Fish and Wildlife Service) and Bonneville both contributed addition funding to provide the necessary infrastructure at the UI to assume the interim drug manufacturing responsibilities, to complete the pivotal data presentations to FDA, and to locate a new drug sponsor. As a result of all these efforts and funding, the scientific studies for efficacy, residue depletion, and target animal safety have all been conducted, the data summarized, and submitted to FDA. The full details of design of these studies, their results, and copies of the original data records have been submitted to the FDA in 16 submissions containing 58 bound volumes. Over 100 bound volumes of additional data and facility records are held in archives at the UI. However, no new drug company sponsor has been located, and the final approval from FDA has not been achieved.

In September 1998, a letter was sent from FDA to the UI, indicating that the last of the required studies (clinical field trials) had been accepted as adequate, but that the FDA still had unresolved questions about potential human risks from use of erythromycin feed additive for salmon that needed to be addressed.

Answering these questions, and responding to FDA in a rapid fashion has been hampered since 1997 by the lack of funding for these activities, and the lack of funding for any infrastructure to deal with these needs. Since the end of 1997, the PI has volunteered more than 500 hr of time and considerable unfunded travel to attend regional meetings, participate in telephone conference calls to keep regional agencies informed about this issue, and to provide the erythromycin product needed for hatchery production. Because this activity has not been associated with adequate funding for the PI or any staff assistance, this mission has not progressed with due diligence.

This project needs adequate support to retrieve, summarize and submit information to more clearly define the risks of the use of erythromycin in salmon culture. Specifically, the FDA is concerned about the risks of development of resistant microorganisms in humans from use of antibiotic therapy in fish. In the recent years, the medical community has demonstrated concern regarding the increased incidence of resistant

strains of human pathogenic bacteria, resulting from improper and increased usage of antibiotics in human and veterinary medicine. Until these issues are resolved, potential drug company sponsors have indicated that they are not willing to step forward to support the manufacture of this product. Without a drug company sponsor to be pro-active with FDA to promote their completion of the process, the priority of this project within the internal review structure languishes.

This project provides support for the PI and for an assistant at the UI to provide a pro-active response to FDA inquiry, to interact with key regional representatives and use their networks and expertise to finalize any data retrieval activities and secure the end to this project. This project provides support for the PI to interact with prospective drug companies about the progress and prospects of support for this product.

References

Austin, B. 1985. Evaluation of antibacterial compounds for the control of bacterial kidney disease in rainbow trout, Salmo gairdneri. Journal of Fish Disease 8:209-220.

Elliott, D. G., R. J. Pascho, and G. L. Bullock. 1989. Developments in the control of bacterial kidney disease of salmonid fishes. Diseases of Aquatic Organisms 6:201-215.

Evenden, A. J., T. H. Grayson, M. L. Gilpin, and C. B. Munn. 1993. Renibacterium salmoninarum and bacterial kidney disease – the unfinished jigsaw. Annual Review of Fish Diseases 1993:87-104.

Greenlees, K. J. 1997. Laboratory studies for the approval of aquaculture drugs. Progressive Fish-Culturist 59:141-148.

Moffitt, C. M. 1991. Oral and injectable applications of erythromycin in salmonid fish culture. Veterinary and Human Toxicology 33:49-53.

Moffitt, C.M. 1992. Survival of juvenile chinook salmon challenged with Renibacterium salmoninarum and administered oral doses of erythromycin thiocyanate for different durations. Journal of Aquatic Animal Health 4:119-125.

Moffitt, C. M. 1998. Field trials of investigational new animal drugs. Veterinary and Human Toxicology 40(supplement 2): 48-52.

Moffitt, C. M., and A. H. Haukenes. 1995. Regional investigational new animal drug permits for erythromycin as a feed additive and injectable drug. Progressive Fish-Culturist 57:97-101.

Peters. K. K., and C. M. Moffitt. 1996. Optimal dosage of erythromycin thiocyanate in a new feed additive to control bacterial kidney disease. Journal of Aquatic Animal Health 8:229-240.

b. Rationale and significance to Regional Programs

This project addresses Section 7 of the Fish and Wildlife Plan, specifically addresses elements of Objective 7.2A.6 regarding fish health policies, and hatchery performance standards, as well as improved propagation under 7.2D.4. Erythromycin therapy is important for prevention and control of bacterial kidney disease, and used in nearly all chinook salmon rearing programs, either as therapeutic therapy if disease outbreaks occur, or for planned prophylactic treatments administered before anticipated stressful times during fish rearing. Erythromycin is used in some coho programs, and in captive brood programs. Management of fish health in the Columbia basin would be severely impacted without access to the substance.

Access to injectable erythromycin is possible through extra label use through veterinary prescription, but access to the feed additives is prohibited by law without experimental INAD permits. At the present time, over 70 hatcheries in the Pacific Northwest are enrolled in the INAD therapy protocols for feed additive applications of erythromycin that are managed by the University of Idaho. The University of Idaho oversees the production of the premix drug product that is used to formulate fish feeds. During the years since 1995, the agencies and tribes in the northwest have used annually from 16,000 - 20,000 lbs of the erythromycin premix to formulate a total of 400,000 to 500,000 lbs of medicated fish feeds that are shipped to and used at agency hatcheries and in captive brood operations.

From the beginning, this project has been well integrated with the needs of the region for therapeutic substances for hatchery production. The field trials used to support the claim of efficacy to FDA were all conducted in hatcheries in Idaho, Washington and Oregon. The original scope of work for the Bonneville contract came from a joint effort by the Pacific Northwest Fish Health Protection Committee, and the Technical Work Groups of the Power Planning Council. The additional support from the Snake River Compensation Program was provided as match for additional Bonneville Support.

The University of Idaho has provided the legal and technical support of maintaining the INAD needed for this therapy. Moreover, since 1995, the University has assumed the role of manufacturer of the substance and has coordinated all purchase of raw ingredients, mixing and provided support for the maintenance of these operations. The University of Idaho and appropriate agencies have memorandum of agreements that define the legal responsibilities of INAD use, and each of these agencies contributes in kind and directly to funding of the tracking of these substances to complete the requirements for continued use of these substances. However, this support from agencies has not covered any of the technical responses for additional information, nor for additional contacts with FDA for resolving these problems.

c. Relationships to other projects

Each of the agencies (Washington Department Fish and Wildlife, Oregon Department of Fish and Wildlife, Idaho Department of Fish and Game, and the US Fish and Wildlife Service) has developed, and provides at agency cost, an infrastructure to manage the experimental applications of erythromycin at their production hatchery facilities until a label from FDA is secured. In 1995, the UI has established MOAs with each agency to define how they would obtain the medicated feed, and how they would report the shipment, use and disposal of this product. One person in each agency is assigned the task of keeping track of the use of medicated feed articles, and reporting to the U of I on a quarterly basis. The U of I compiles these reports and submits them to FDA. Each of the agencies is billed a sum each year by UI (based on number of hatcheries) to cover costs of reporting drug used, and for organizing the manufacture of the drug needed for sustaining hatchery production in these states. In states with a large number of hatcheries, costs of maintaining the infrastructure within their agency can be substantial. However, without money to support the infrastructure at the U of I to pursue the outstanding elements of the registration program, this INAD structure will continue only on an interim basis. It is not secure without funding for follow up with FDA.

Since 1996, Washington Department of Fish and Wildlife (through Kevin Amos) has assisted some of these follow up details regarding environmental assessment by obtaining samples of sediments for research on the degradation of erythromycin in aquaculture sediments. Amos participated in the video conference call in spring of 1998 and currently chairs the sub committee on therapeutants of the PNFHPC. Amos has been a key leader in increasing the visibility of the project, and will be utilized by this project as a vocal and effective spokesperson, and provider of oversight.

In conference calls October 1998, the Oregon Department Fish and Wildlife, and Idaho Department of Fish and Game offered to provide data to assist with the summary of resistant microorganisms. Some of these data have been provided but they need to be organized, and presented. Furthermore, there are other follow up items that need to be collected. The Oregon Department has a strong research arm in their pathology division and will provide more information.

FWS have volunteered to take the responsibility of INAD infrastructure for the tribal use, through the Nez Perce hatchery system. The FWS staff are well connected to pursue issues of drug registration at the National level. Ray Brunson Olympia Fish Health Laboratory is the executive secretary of the PNFHPC and assists with distribution of information regarding registration of erythromycin. This project will link more closely to the PNFHPC and use this vehicle for oversight. Cathy Clemens of the Dworshak Fish Health Center has volunteered some staff assistance for library work.

This project is critical to the Chinook Captive Broodstock Project. The PI has been asked several times to attend meetings of the Chinook Captive Broodstock Project, but has not had any funding to allow this. They have sought consultation with UI regarding some of the problems that they have with erythromycin toxicity, and the UI would be a good partner to join any research programs studying erythromycin toxicity. With BPA providing funding for a more active role by UI, will be able to play a more active role and improve the success of their studies.

d. Project history (for ongoing projects)

Not applicable

e. Proposal objectives

OBJECTIVE 1. Provide an infrastructure to keep erythromycin registration efforts viable in the Columbia River Basin.

OBJECTIVE 2. Increase visibility and dialog of project with FDA to resolve outstanding issues.

OBJECTIVE 3. Assemble team of fish health and other scientists' expertise to assist in design or implementation of any additional studies or data to resolve outstanding issues

f. Methods

The duration of this project is variable because the tasks are based on adaptive approaches that are fashioned by the responses received. The proposed duration of funding is two years, to allow for adequate time to complete milestones of progress for each objective.

OBJECTIVE 1. Provide an infrastructure to keep erythromycin registration efforts viable in the Columbia River Basin.

To provide a secure infrastructure, this project will provide funding for the PI and for a part time assistant for the PI to manage this project. This assistant will work under the direction of the PI to:

1) maintain archives of all data and communications with FDA and keep current all aspects of the INAD management to provide access for erythromycin during FDA negotiations.
2) assemble additional summaries of scientific (peer reviewed) and grey literature regarding antibiotic resistance in fish for the FDA, and for any other data needs required to satisfy FDA or other regulatory agencies regarding the safety of applications of erythromycin feed additive in hatcheries.
3) establish a working relationship with key regional personnel, using the umbrella of the Pacific Northwest Fish Health Protection Committee, subcommittee on therapeutic substances. Develop a mechanism within this structure to provide oversight for this project.
4) assist in providing active dialog with potential drug companies to obtain active support for the manufacture of this compound after the outstanding details with FDA are resolved.

These first three activities will begin immediately upon funding of this project. Activity 4 will begin at then end of the year, after progress with FDA is made.

The part time staff person will be trained to organize and maintain all archives of FDA submittals, records of correspondence with FDA and activities of reporting on INAD activity. The requirements by FDA are such that records of all communications must be maintained for at least 3 years after the final drug approval. Since we have not had a final drug approval, we must keep building these records. We will work to make the archival system up to date and easy to access.

We will complete follow up responses to FDA questions in a rapid manner, and make a calendar of progress for distribution to the PNFHPC. We will work to define a structure within PNFHPC for project oversight. Kevin Amos has provided assistance for several years as a liaison, and we will work to make this a permanent system.

Once progress with FDA has been achieved, we will begin to dialog with appropriate drug companies to take over the sponsorship of this project.

OBJECTIVE 2. Increase dialog and visibility of this project with FDA staff and others to resolve outstanding issues in an expeditious fashion.

We will begin a pro-active dialog with FDA, using several approaches to raise the level of awareness about the importance of this issue to the resources of the Columbia Basin. We will communicate directly with Dr. Tom Bell, Center for Veterinary Medicine's lead aquaculture staff, and with liaisons through the NRSP-7 (Department of Agriculture) program such as Dr. Meg Oeller, FDA liaison for NRSP-7. In late 1999, we will assemble a meeting of key FDA staff with pivotal fish health and management personnel from the northwest. Last spring (1998), Kevin Amos, Washington Department of Fish and Wildlife participated in a video conference call with key FDA staff to determine the status of the languishing approval process. At the time of that call nearly a year had passed since the UI submittal of data from clinical field trials. This event increased the level of awareness of our needs within FDA and resulted in the NRSP-7 liaison agreeing to take a more active role in the review and approval process.

The meeting in fall 1999 will build on efforts from 1998, but will include 2 - 3 more key regional leaders, including higher level administrators from agencies in this dialog. The PI will travel to FDA for face to face meeting and follow up dialog.

By increasing the visibility of our project and its needs, through this increased agency partnership, we will raise the general awareness, and this will expedite review and approval. The PI will attend FDA workshops held at international aquaculture meetings (Aquaculture America Meeting, January 2000) and present papers at fish health meetings (American Fisheries Society) and at the International Meeting on Risk Assessment in Aquaculture, February 2000). The PI and assistant will began a pro-active communication with the National aquaculture Coordinator to garner assistance through that avenue.

OBJECTIVE 3. Assemble regional fish health and other scientists to assist in design or implementation of any additional studies determined after dialog with FDA.

Using the linkages provided by the PNFHPC, the PI and staff assistant will attend meetings of this group (twice each year) and will provide updates on the progress of the project. In addition, UI will convene regular communications with key members of PNFHPC to accomplish the project objectives. Considerable progress was achieved in the fall of 1998 through two telephone conferences organized by the U of I, and the subcommittee on therapeutants of PNFHPC. Funding from this project will cover costs of providing and organizing monthly exchanges of information and updates. We will use these contacts to further the answers to any queries. We will utilize funding from this project to complete peer reviewed publications from all the scientific research. These publications will enhance the visibility of the research, and provide materials for dissemination to other scientists and managers.

We will begin active communications with the National Center for Toxicological Research, a FDA laboratory in Jefferson, Arkansas, that has been assigned the responsibility of determine the fate of erythromycin in aquacuture sediments. Microbiologists at this site are also able to screening samples of sediments for microbiological flora. Due to lack of available funds at the UI, the PI has not NCTR since 1995. UI and Dr. Jarij Pothluri of NCTR collaborated on a preliminary project that defined the methods to determine degradation of erythromycin in sediments (Assaf et al in review). Adequate funding of this collaboration will allow UI to help provide to NCTR any additional samples from regional hatcheries in a rapid and expeditious manner. The PI from UI will travel to NCTR to improve dialog and progress in this project.

References

Assaf, N. A., J. V. Pothuluri, R. Wang, and C. E. Cerniglia and C. M. Moffitt. In review Bioassay Procedure for the evaluation of erythromycin activity in aquaculture and the environment. Journal World Aquaculture Society.

g. Facilities and equipment

The University of Idaho has adequate office space, computer resources and storage facilities to provide for data acquisition, data analysis or archival needs. Copies of all submissions and all original records from studies submitted and not submitted to FDA are stored in file cabinets and binders in the Department of Fish and Wildlife Resources. The University has site licenses for SAS and other data analysis programs, and the Statistical Consulting Center in the Division of Statistics has full time faculty and staff assistance available by appointment throughout the year. If additional studies are defined through Objective 2, we will identify through Objective 3 the most suitable staff and facilities for the additional studies

h. Budget

Budget Justification

Personnel costs are for a staff assistant (50% FTE) and for the Principal Investigator (25% FTE). This staff structure will provide the infrastructure needed to respond to the needs of this project.

Benefit rates are 28.5% for the PI and 34.5% for the staff assistant.

Travel request covers costs economy airfare, ground transportation, lodging, meals, registration, and misc. expenses required to attend 2 meetings within the region (with the PNFHPC); attend 2 meetings with FDA (Rockville MD); present a paper at the AFS fish health section meeting (to be determined); meet with aquaculture drug leaders at "Aquaculture America" meeting in Louisiana and visit to National Center for Toxicological Research, Arkansas; and present a paper and attend the Risk Assessment in Aquaculture meeting in Paris France.

Indirect cost rate for the College of FWR experiment station is 31.5%

Section 9. Key personnel

Christine M. Moffitt, Principal Investigator, 25% time.

Extensive expertise in erythromycin therapy for bacterial kidney disease, and other areas of fish health management. Author of more than 25 publications on erythromycin and aquaculture drugs in fish culture. Moffitt will serve as primary source for contacts, and for information for presentation and dialog with FDA. Moffitt will supervise staff assistant.

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EDUCATION

Ph.D., Fisheries Biology, 1979, University of Massachusetts, Amherst
M.A., Biological Sciences, 1973, Smith College, Northampton, Massachusetts
B.A., Biology, 1969, University of California, Santa Cruz, California

POSITIONS HELD (LAST 10 YRS)

1997, Research Associate Professor, Department of Fish and Wildlife Resources
1989-1996, Adjunct Associate Professor, Department of Fish and Wildlife Resources
1983-1989, Adjunct Assistant Professor, Department of Fish and Wildlife Resources, University of Idaho

SELECTED PUBLICATIONS (5 from recent 2 years)

Moffitt, C. M. and seven coauthors. 1998 Pathogens and diseases of fish in aquatic ecosystems: implications in fisheries management. Journal of Aquatic Animal Health 10:95-100.

Moffitt, C. M. 1998. Field trials of investigational new animal drugs. Veterinary and Human Toxicology 40(supplement 2):48-52.

Haukenes, A. H. and C. M. Moffitt. 1998. Concentrations of erythromycin in maturing chinook salmon following intraperitoneal injection of one of two drug formulations. Journal of Aquatic Animal Health 10 (in press)

Moffitt, C. M. and Y. Kiryu. 1998. Toxicity, teratogenesis, and efficacy of injectable erythromycin (Erythro-200) administered repeatedly to adult spring chinook salmon. Journal of Aquatic Animal Health. (in press)

Peters, K. K. and C. M. Moffitt. 1996. Optimal dosage of erythromycin in a new feed additive to control bacterial kidney disease. *Journal of Aquatic Animal Health.* 8:229-240.

Section 10. Information/technology transfer

UI will provide submissions of data and summaries of information for FDA through coordinated efforts with regional fish health professionals and other scientists to resolve uncertainties regarding the risks regarding development of resistant microorganisms. The PI will continue to produce peer-reviewed publications, and reports to provide all information on erythromycin therapy to fishery managers and fish health scientists.

Congratulations!